44. (Once amended) The device of claim 40, wherein the polyimide coating is formed by applying a photocurable polyimide pre-cursor on core of the haptic, and then curing the polyimide pre-cursor.

47. (Once amended) The device of claim 46 wherein the surface of the haptic core is treated by corona discharge.

48. (Once amended) The device of claim 46 wherein the surface of the haptic core is treated by an oxidizing agent.

49. (Once amended) The device of claim 40, wherein the surface of the haptic core at least on the distal end has been treated before the coating has been applied by contacting the haptic core with an adhesion promoter effective to enhance the bond strength of the polyimide coating to the haptic core.

51. (Once amended) The device of claim 40, wherein the polyimide coating is formed by treating at least a portion of the surface of the haptic core, applying a photocurable polyimide pre-cursor to the treated region, and curing the polyimide pre-cursor.

REMARKS

Claims 1, 4-8, 16, 17, 19-22, 40, 43, 44, 47-49 and 51 have been amended. These amendments do not contain new matter and are fully supported by the specification. After these amendments are entered, thirty three (33) claims (Claims 1, 2, 4-17, 19-22, 24-40 and 42-53) remain pending in this application through this Amendment.

Rejections Under 35 USC 112

Claims 4-7 and 19-22 have been amended to overcome the 35 U.S.C. §112, second paragraph, rejections set forth in the Office Action.

Rejections Under 35 USC 102(b)

Claims 1-3, 5, 7, 9-14, 40-42, and 44-53 were rejected under 35 USC 102(b) as being anticipated by Patel (US 5,252,262). For the following reasons, the Examiner's rejection is respectfully traversed.

The present invention relates to an intraocular lens (IOL) wherein **the optic and haptic are integrally formed of one polymeric material**. By the phrase integrally formed, it is meant that the optic and haptic are **monolithically formed**, that is, cast as a single piece (Page 5, lines 1-2). Because the optic is required to be made from a biologically inert and optically transparent material, such as polymeric silicone, haptics made from this material would not promote the fibrosis necessary to anchor the haptics to the surrounding tissue. This may lead to poor fixation and consequent migration or dislocation of the IOL. To solve this problem, a polyimide coating is applied on the core of the haptic at least on a distal end away from the optic of an IOL of the present invention.

In contrast to the present invention, Patel teaches an intraocular lens, wherein **the haptic is first formed separately from the optic and then attached to the optic by using laser welding** (col. 4, 21-57). Moreover, Patel teaches that at least the end portion of the haptic to be attached to the optic **must be colored material** (i.e., containing a pigment or a dye) so that the pigment or dye in haptic absorbs the energy of laser that passes through transparent optic (col. 4, lines 21-57 and col. 5, lines 15-34). Absorption of the laser energy by the pigment or dye then insures that the end portion of the haptic can be heated to a temperature sufficient for melting the end portion and fusing the end portion to the optic. Unlike Patel, the present invention does not need at all a pigment or a dye.

In sum, Applicants submit that Patel discloses a different intraocular lens. Applicants submit that the claimed invention are not anticipated by Patel, since the cited reference does not contain all of the elements of the claimed intraocular lens and since the present invention does not contain all of the elements of the Patel's intraocular lens. Applicants respectfully request withdrawal of the 35 U.S.C. §102(b) rejection.

Rejections Under 35 USC 103(a)

Applicants believe that a brief description of the present invention as claimed will assist the prosecution. The present invention provides an IOL, in which the fixation member or members, haptic(s), is (are) integrally attached or formed with the optic from one polymeric material to achieve high pull strengths; and the distal end portion of the fixation member(s) is modified by applying a polyimide coating thereon to achieve a surface that will suitably promote fibrosis in the eye, thereby anchoring the IOL to the surrounding physiological structure. Because the optic and fixation member are integrally formed, there is little or no risk of the fixation member being separated from the optic. By the phrase

integrally formed, it is meant that the optic and haptic are monolithically formed, that is, cast as a single piece. And because the surface of the haptic can be treated to achieve suitable fibrosis promotion for anchoring, there is no concern about the biological inertness of the polymeric material that is used to form the core of the haptic and optic.

Claims 1-3, 5, 7, 9-14, 40-42, and 44-53 were rejected under 35 USC 103(a) as being anticipated by patel (us 5,252,262) in view of Bruns et al (US 4,737,322). For the following reasons, the examiner's rejection is respectfully traversed.

Patel does not teach the applicant's invention as now claimed and the pending claims are patentable over Patel for the various reasons stated above.

Bruns et al disclose that an intraocular lens comprises an optic and a haptic, wherein the haptic is composed of a material (e.g., polyimide) having relatively high temperature resistance sufficient to withstand typical autoclave temperature and pressures and wherein the haptic can be fabricated in a wide variety of engineered configurations. Bruns et al do not disclose or suggest anything about the monolithic formation of both the haptic and optic from one polymeric material and thereby do not fill the gaps left by Patel (US 5,252,262).

In sum, Applicants submit that none of the two cited references discloses or suggests anything about an intraocular lens comprising an optic and a haptic, wherein both the haptic and the optic are monolithically formed from one material. Applicants further submit that, since Patel requires a dye or pigment present in the haptic so as to allow the haptic to be attached to the optic using laser welding, the cited references would not motivate one skilled in the art to combine teachings of the cited reference to arrive at the present invention. Applicants submit that a *prima facie* case of obviousness can not be established and request withdrawal of the 35 U.S.C. §103(a) rejection.

The Examiner has rejected claims 4, 6 and 8 under 35 U.S.C. 103(a) as being unpatentable over Patel in view of Bruns et al and further in view of Patel et al (US 6,158,862). For the following reasons, the Examiner's rejection is respectfully traversed.

These claims are patentable over Patel in view of Bruns et al for the various reasons stated above. US 6,158,862 fails to disclose or suggest that the haptic and the optic are monolithically formed of one polymeric material. Moreover, there is no motivation in Patel et al for making the necessary changes to its disclosure to obtain the invention as claimed in claims 4, 6 and 8. Since US 6,158,862 does not fill the gaps left by these references, claims 4, 6, and 8 remain patentable.

The Examiner has rejected claims 15-18, 20, 22 and 43 under 35 U.S.C. 103(a) as being unpatentable over Patel in view of Bruns et al and further in view of Cumming (US 5,047,051). For the following reasons, the Examiner's rejection is respectfully traversed.

These claims are patentable over Patel in view of Bruns et al for the various reasons stated above. Cumming fails to disclose or suggest that the haptic and the optic are monolithically formed of one polymeric material. Moreover, there is no motivation in Cumming for making the necessary changes to its disclosure to obtain the invention as claimed in claims 15-18, 20, 22 and 43. Since Cumming does not fill the gaps left by these references, claims 15-18, 20, 22 and 43 remain patentable.

The Examiner has rejected claims 19 and 21 under 35 U.S.C. 103(a) as being unpatentable over Patel, Bruns et al, and Cumming and further in view of Cumming (US 5,047,051). For the following reasons, the Examiner's rejection is respectfully traversed.

Claims 19 and 21 are patentable over Patel, Bruns et al and Cumming for the various reasons stated above. Since Patel et al does not fill the gaps left by these references, claims 19 and 21 remain patentable.

In summary, Applicants submit that pending claims 1, 4-8, 16, 17, 19-22, 40, 43, 44, 47-49 and 51 are not obvious over the cited references, since none of the cited references, alone or in combination with others, teaches or suggests anything about the Applicants invention, and since none of the cited references, alone or in combination with others, provide any motivation for making the necessary changes to its disclosure to arrive at the claimed invention. Applicants respectfully request reconsideration and withdrawal of the claim objections and rejections set-forth in the Office Action and allowance of claims 1, 4-8, 16, 17, 19-22, 40, 43, 44, 47-49 and 51.

Version with Markings to Show Changes Made

In the claims:

Please amend claims 1, 4-8, 16, 17, 19-22, 40, 43, 44, 47-49 and 51 as follows:

1. (Twice amended) An intraocular lens for surgical implantation in the eye, the lens comprising:

an optic, and

at least one haptic connected to the optic and having a core and a polyimide coating over the core at least on a distal end away from the optic;

wherein the optic and haptic core are monolithically formed from one polymeric material selected from the group consisting of [comprise]a silicone polymer, an acrylic polymer, a hydroacrylic polymer, a 2-hydroxyethylmethacrylate polymer, a polymethylmethacrylate polymer, and [or]combinations thereof.

4. (Twice amended) The intraocular lens of claim 1 wherein the polymeric material is silicone polymer.

5. (Twice amended) The intraocular lens of claim 1 wherein the polymeric material is acrylic polymer.

6. (Twice amended) The intraocular lens of claim 1 wherein the polymeric material is 2-hydroxyethylmethacrylate polymer.

7. (Twice amended) The intraocular lens of claim 1 wherein the polymeric material is polymethylmethacrylate.

8. (Once amended) The intraocular lens of claim 1 wherein the optic comprises [a polymer incorporating]a UV absorbing compound.

16. (Twice amended) An intraocular lens comprising:

an optic; and

two plate haptics diametrically opposed and extending radially away from the optic, each of the haptics having a groove [in a]at distal peripheral end[edge, the groove having a polyimide material placed therein];

wherein the interior of the groove has a polyimide coating thereon and wherein the optic and the plate haptics are monolithically formed from one polymeric material selected from the group consisting of [comprise]a silicone polymer, an acrylic polymer, a hydroacrylic polymer, a 2-hydroxyethylmethacrylate polymer, a polymethylmethacrylate polymer, and [or]combinations thereof.

17. (Once amended) The intraocular lens of claim 16 wherein the optic [and haptics are integrally formed]comprises a UV absorbing compound.

19. (Twice amended) The intraocular lens of claim 16 wherein the polymeric material is silicone polymer.

20. (Twice amended) The intraocular lens of claim 16 wherein the polymeric material is acrylic polymer.

21. (Twice amended) The intraocular lens of claim 16 wherein the polymeric material is 2-hydroxyethylmethacrylate polymer.

22. (Twice amended) The intraocular lens of claim 16 wherein the polymeric material is polymethylmethacrylate.

40. (Amended three times) A device for implantation in a human to be anchored in a secured position within human tissue, the device comprising:

a biologically inert exterior surface region; and

a polyimide coating on at least a portion of said region, the coating sufficient to be effective to promote fibrosis of the surrounding tissue with the polyimide to enhance the anchoring of the device to the surrounding tissue;

wherein the device is shaped in the form of an intraocular lens, the intraocular lens comprising an optic and at least one haptic, the haptic having a core, wherein said polyimide coating is on said core; and

wherein the optic and the haptic core [comprise]are monolithically formed from one polymeric material selected from the group consisting of a silicone polymer, an acrylic polymer, a hydroacrylic polymer, a 2-hydroxyethylmethacrylate polymer, a polymethylmethacrylate polymer, and [or]combinations thereof.

43. (Twice amended) The device of claim 40, comprising two haptics shaped in the form of a plate, diametrically opposed and extending radially away from the optic, each of the haptics having a groove [in a]at distal peripheral end[edge], wherein the interior of the groove has a polyimide coating thereon[having the polyimide material therein].

44. (Once amended) The device of claim 40, wherein the polyimide coating is formed by applying a photocurable polyimide pre-cursor on [at least the distal end]core of the haptic, and then curing the polyimide pre-cursor.

47. (Once amended) The device of claim 46 wherein the surface of the haptic core is treated by corona discharge.

48. (Once amended) The device of claim 46 wherein the surface of the haptic core is treated by an oxidizing agent.

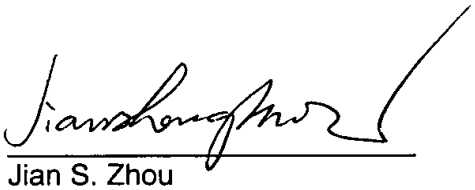
49. (Once amended) The device of claim 40, wherein the surface of the haptic core at least on the distal end has been treated before the coating has been applied by contacting the haptic core with an adhesion promoter effective to enhance the bond strength of the polyimide coating to the haptic core.

51. (Once amended) The device of claim 40, wherein the polyimide coating is formed by treating at least a portion of the surface of the haptic core, applying a photocurable polyimide pre-cursor to the treated region, and curing the polyimide pre-cursor.

Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned.

Please address all correspondence to Thomas Hoxie, Novartis Corporation, Patent & Trademark Department, 564 Morris Ave., Summit, NJ 0790-1027. The Commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §§1.16 and 1.17, or credit any overpayment, to Deposit Account No. 19-0134.

Respectfully submitted,



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Date: February 27, 2002

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